# PATENT SPECIFICATION

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(21) Application 4546/74 (22) Filed 31 Jan. 1974
(31) Convention Application No. 2306552
(32) Filed 10 Feb. 1973 in
(33) Germany (DT)
(44) Complete Specification published 29 Sept. 1976
(51) INT CL² A61F 1/24 F16C 11/06
(52) Index at acceptance
A5R X6
E2F 1T1

(19) THE PATENT OFFICE LONDON

## (54) IMPROVEMENTS IN JOINT ENDOPROSTHESES

(71) We, FRIEDRICHSFELD GMBH, Steinzeug- und Kunstoffwerke, a German corporate body, of D 68 Mannheim 71, Postfach 7, Steinzeugstr. 50, Germany, do hereby declare the invention for which we pray that a patent may be granted to us and the method by which it is to be performed to be particularly described in and by the following statement:—

The present invention relates to improvements in joint endoprostheses.

For the construction of joint endoprostheses, the following constructions and material combinations have so far been used or proposed:

1) Prostheses of metal, initially starting with stainless steels. After it was recognised that these steels are capable of corrosion in animal tissue, special CoCr-Mo alloys were developed whose corrosion properties are more favourable. However, these alloys do not have the mechanical properties of the very hard steels, in particular, as regards resistance to creep. Frictional stress between metal and metal in the environment of animal tissue should be avoided as far as possible since the metal corrosion arising from it leads to tissue damage.

2) Joint endoprostheses are therefore often made of the combination metal-plastics for the surfaces which are in sliding contact with one another, e.g. for replacement hip joints. However, frictional wear occurs which necessitates exchange of the plastics parts after 5 to 10 years.

3) Joint endoprostheses of ceramic, particularly of substantially non-porous $Al_2O_3$-ceramic, have the advantage of only very slight wear under frictional stress and the few wear particles thus arising do not damage the body. After the period of settling down, no further wear occurs. Corrosion phenomena have not been observed with $Al_2O_3$-ceramic. Histological investigations of the tissue adjoining $Al_2O_3$-ceramic implants have showed no rejection as with metals and plastics. Reactions of growing on to and into prostheses have been observed.

4) Joint endoprotheses of ceramic-metal composite construction have also become known, namely as hip joint replacements consisting of an acetabulum which is fixed in the hip and a head of $Al_2O_3$-ceramic, with the head being fixed to a metal shaft by means of a peg protruding into the head, the metal shaft being anchored in the femur. In this construction, the favourable properties of ceramics as regards frictional stress are made use of but the strength and creep resistance of the alloys concerned are unsatisfactory as already mentioned above.

As a protection for metal prostheses against corrosion in animal tissue, it has also been proposed that the surface parts of metal endoprostheses which serve for fixation in a bone should be coated with porous ceramics. However, due to the porosity of the ceramics direct contact is established between the metal parts and the tissue, namely through the pores, so that the only metals which can be considered are the above-mentioned corrosion-resistant alloys. Very hard steels cannot be used.

Vitreous ceramic materials of various kinds and with different degrees of devitrification have also been investigated for their suitability as endoprostheses, and a body tolerance was found which resembled that of ceramics. However, the mechanical properties, in particular the bending strengths, do not allow the construction of complete joint endoprostheses of vitreous ceramic material.

Hitherto, two methods of fixing joint endoprostheses in an adjoining bone space have been used. One method uses direct contact between prostheses and bone, mostly under mechanical stress through driving the prostheses into the bone. With metal endoprostheses, this kind of anchorage, also termed cement-free fixation, has not led to satisfactory results since the prostheses often become loose due to the above-mentioned rejection reactions of the body tissue. Now, joint

endoprostheses are therefore mostly fixed in the adjoining bone by means of plastic cements. There are, however, in this case certain operating difficulties which are connected with the kind of hardening reaction of the cements. Moreover, the hardened plastic evokes a defensive reaction of the surrounding tissue.

According to the invention, there is provided a joint endoprosthesis comprising an articular part of substantially non-porous $Al_2O_3$-ceramic which will, in use, be subject to sliding frictional contact, and a fixing part for fixing the prosthesis in a bone shaft, wherein the fixing part is made of high strength steel and is provided with at least one substantially non-porous glass or glass-like coating on those surfaces which will, in use, come into contact with animal tissue.

The present invention will be better understood from the following description of embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a part sectional view of a hip joint endoprosthesis,

Figure 2 is a sectional view of an elbow joint endoprosthesis, and

Figure 3 is a sectional view of the elbow joint endoprosthesis of Figure 2, perpendicular to the plane of the section of Figure 2.

In Figure 1, the fixing part 1 of the femur part of the prosthesis, in the form of a shaft, is seated in the femur up to the collar 2 and is partially supported by this collar 2 on the bone. This shaft 1 consists of very hard steel possessing high creep resistance and is provided on all surfaces, except on those facing a generally spherical articular part or head 3, with a substantially non-porous glass or glass-like coating. At its upper end, the shaft carries a peg or pin 4, with a flat to prevent torsion, which fits into a corresponding recess in the articular head 3. The facing surfaces 5 of the articular head 3 and the shaft 1 are flat, e.g. ground. The articular head 3 consists of substantially non-porous $Al_2O_3$-ceramic. In general, it is fixed to the shaft along the surfaces of the peg 4 with a suitable adhesive after the shaft has been implanted in the femur. The external surface of the articular head 3 made of $Al_2O_3$-ceramic is polished. The internal surface of an $Al_2O_3$-ceramic acetabulum 6 is polished to fit the external surface of the articular head 3. The acetabulum 6 carries various grooves on its reverse side 7 by means of which a direct fixation in the pelvic bone is obtained.

The elbow joint prosthesis of Figures 2 and 3 consists of two fixing parts 8 and 9, in the form of shafts, of a very hard steel possessing a high creep resistance, and two articular parts 10 and 11 of substantially non-porous $Al_2O_3$-ceramic which are movable against each other. The shafts 8 and 9 are provided with a substantially non-porous glass or glass-like coating on all surfaces except those with which they contact the parts 10 and 11 made of $Al_2O_3$-ceramic. After implantation of the shafts 8 and 9, pegs or pins 12, 13 are generally fitted into corresponding recesses in the $Al_2O_3$-ceramic parts 10 and 11 respectively and the parts fixed along the pegs 12 and 13 with a suitable adhesive. The facing surfaces 14 and 15 of the shafts 8 and 9 and the $Al_2O_3$-ceramic parts 10 and 11 are flat, e.g. ground. The surfaces of the $Al_2O_3$-ceramic parts 10 and 11 which slide on each other are polished to fit each other.

Steels with a very high tensile strength which can be considered are very hard steels which retain or almost retain this high tensile strength at body temperature and also after a large number of load cycles. To achieve exact dimensions, the tensile strength remaining after a large number of load cycles must be used as the bases of design. Moreover the steel used must be able to withstand the heat treament required for the application of the glass or glass-like coating if possible without loss of strength, or the value of strength obtaining after this heat treatment must be used for the dimensioning. If the glass or glass-like coating is applied by a flame spraying method or another method affecting the surface of the steel, then the change in strength of the steel part is in most cases only slight.

By "$Al_2O_3$-ceramic", a dense, i.e. showing no open porosity, oxide ceramic with more than 85% by weight of $Al_2O_3$ is to be understood. The most advantageous ceramic is an oxide ceramic with more than 95% by weight of $Al_2O_3$.

By the term "substantially non-porous glass or glass-like coating", one or more layers of glass, vitreous enamel or vitreous ceramic is to be understood, which layer or layers adhere firmly to the steel of the shaft, if need be by means of one or more metallic, for instance galvanically applied, intermediate layers. Methods of applying such layers are known.

The chemical composition of these coatings and the degree of devitrification in the case of vitreous ceramics are determined by their tissue tolerance. Favourable compositions which fulfill these conditions are already known.

In many cases it is of advantage to apply in addition an outer porous layer of ceramic, e.g. $Al_2O_3$-ceramic, to the substantially non-porous glass or glass-like coating in order to improve the fixation thereto of growing tissue. The first substantially non-porous glass or glass-like

layer then excludes all contact of the tissue with the metal and thus also any dissolution of metal ions in the tissue. The second, porous layer only serves to give a better fixation of the prosthesis in the tissue.

There are thus provided joint endoprostheses which take advantage of the favourable wear properties of dense $Al_2O_3$-ceramic for joint parts under frictional stress, whereas for the fixation in the bone shaft the favourable mechanical properties of very hard steels can be taken advantage of by the fact that these steels, which in themselves are not corrosion-resistant in an animal host, are protected from contact with the tissue by at least one substantially nonporous glass or glass-like coating.

WHAT WE CLAIM IS:—

1. A joint endoprosthesis comprising an articular part of substantially non-porous $Al_2O_3$-ceramic which will, in use, be subject to sliding frictional contact, and a fixing part for fixing the prosthesis in a bone shaft, wherein the fixing part is made of high strength steel and is provided with at least one substantially non-porous glass or glass-like coating on those surfaces which will, in use, come into contact with animal tissue.

2. A joint endoprosthesis according to claim 1, wherein the coating consists of vitreous enamel.

3. A joint endoprosthesis according to claim 1, wherein the coating consists of vitreous ceramic.

4. A joint endoprosthesis according to claim 1, wherein the fixing part is provided with an outer porous ceramic layer.

5. A joint endoprosthesis substantially as herein described with reference to Figure 1 or Figure 2 of the accompanying drawings.

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Reference has been directed in pursuance of section 9, subsection (1) of the Patents Act 1949, to patent No. 1,334,584.

Printed for Her Majesty's Stationery Office, by the Courier Press, Leamington Spa, 1976
Published by The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

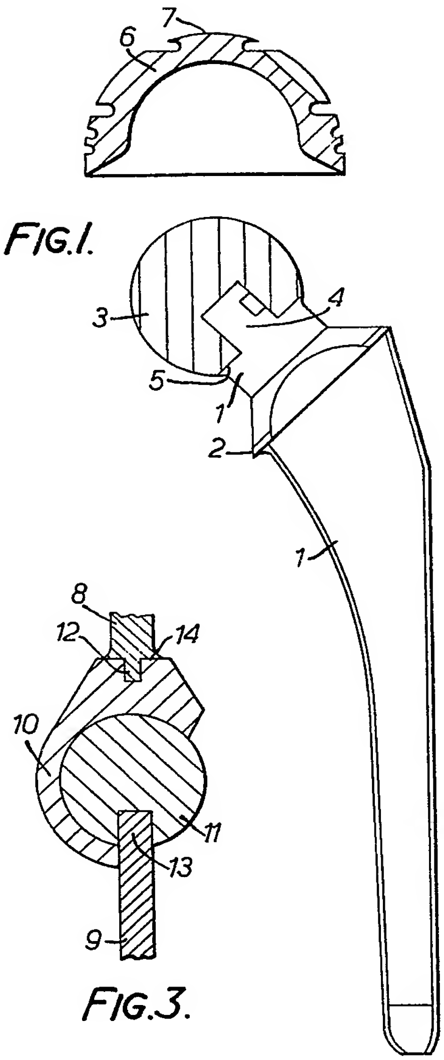


FIG.1.

FIG.3.

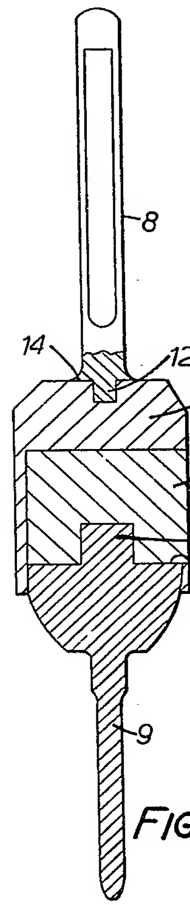


FIG.2.